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Atty Dkt. No. IFT-5657A-2

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Patent Application Of: )  
Kipp et al. )  
For: METHOD FOR PREPARING )  
SUBMICRON PARTICLE )  
SUSPENSIONS )  
Serial No.: 10/021,692 )  
Filed: December 12, 2001 )  
Examiner: Simon J. Oh )  
Art Unit: 1615 )  
Conf. No. 9772 )

### CERTIFICATE OF MAILING

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August 4, 2004.

Judith L. Goldberg

### DECLARATION

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22202

Sir:

I, Mark Doty aver as follows:

1. I am over the age of twenty-one years and make these statements from my own personal knowledge.
2. I have received a Bachelors Degree in Chemical Engineering from the University of Minnesota in 1987 and a Doctor of Philosophy Degree in Chemistry from Iowa State University in 1995.
3. I have been employed by Baxter since 1995 and currently hold the position of Associate Director of Research.
4. I am a joint inventor on U.S. Patent Application Serial No. 10/021,692.
5. I have reviewed the claims of this application and I believe that the claimed invention was conceived prior to January 7, 2000 and I have diligently worked on this project since this time.
6. As evidence of this I have attached laboratory notebook pages with dates redacted. The laboratory notebook pages are not necessarily the earliest date of conception of

the claimed invention and do not represent the results of an exhaustive search for evidence of the earliest date of conception or reduction to practice.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, I acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and may jeopardize the validity of the application or any patent issuing thereon.

Date: August 4, 2004

BY   
Mark J. Doty



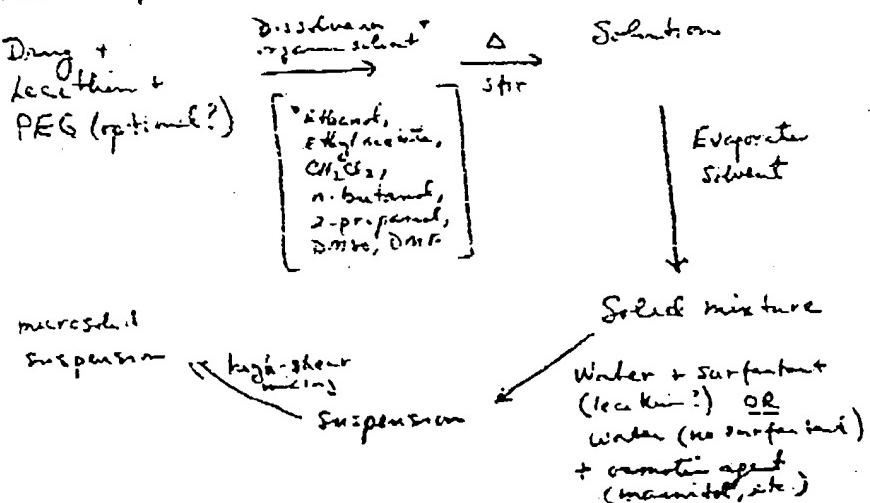
Solv. Dispersion of Prednisolone - Lecitin

F.M. 170

Notebook

Purpose:

Test the hypothesis that one can make nanocrystals (or minimize particle size in a microsuspension) by first preparing a solid dispersion of the drug in a matrix such as PEG (polyethylene glycol) and/or phosphatidyl choline (or lecithin). The solid is then re-dissolved in an aqueous solvent (water + surfactant). Hopefully! high shear mixing (stirring; homogenization?) will cause breakdown of the solid to form nanocrystals (or micronized monomorphed drug) in suspension.

General procedure:

I will first attempt to prepare a 1% prednisolone suspension using a 5% (w/w) solid dispersion of drug + lecithin (or egg phosphatidyl choline). This solid will be ~~then~~ dispersed in an aqueous medium (water + mannitol). Call this formulation FORMULATION I.

40

J. S. Kipp

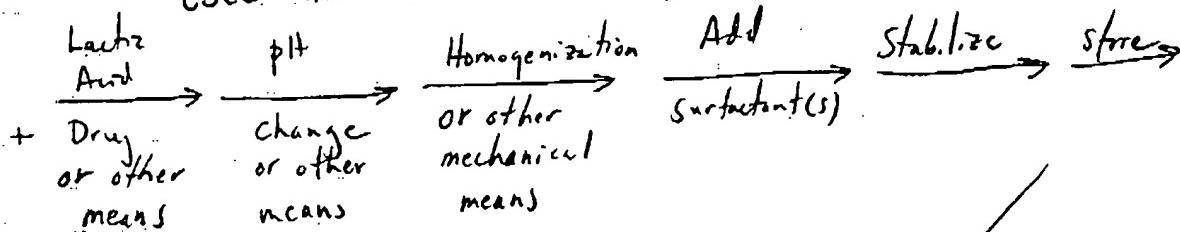
Mah Jit



BOOK NO. 20813 - 60

## pH-precipitation of Lactic Acid Prior to Homogenization

Purpose: Note an idea. Use pH-induced precipitation of Intramazole prior to homogenization to reduce particle size. Use lactic acid to solubilize the drug. (See Chem. Pharm. Bull., 46(8), 1333-1334 (1998).



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\*\* TOTAL PAGE.03 \*\*

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